Vallum Corporation
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

July 2, 2018

Re: K173864
Trade/Device Name: Peekplus® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 4, 2018
Received: June 5, 2018

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173864

Device Name
Peekplus® Interbody Fusion Device

Indications for Use *(Describe)*
The Peekplus® Interbody Fusion Device ("Peekplus Device") is indicated for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Peekplus® devices are to be used with autogenous bone graft material and supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Vallum Corporation's Peekplus® Interbody Fusion Device

Submitted by
Vallum Corporation
61 Spit Brook Road
Nashua, NH 03060
Phone: 603-577-1989
Contact Person: Maureen O'Connell

Device Name and Address of Sponsor
Vallum Corporation
61 Spit Brook Road
Nashua, NH 03060
Phone: 603-577-1989
Contact Person: Stephen Blinn

Preparation Date
June 1, 2018

Device Name
Peekplus® Interbody Fusion Device

Common Name
Intervertebral Body Fusion Device

Classification
Orthosis, Spinal Intervertebral Fusion

Purpose of Submission
New device

Primary Predicate Device
Binder Biomedical Inc. Intervertebral Body Fusion Device (K093015)

Intended Use / Indications for Use
The Peekplus® Interbody Fusion Device ("Peekplus Device") is indicated for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade 1

spondylolisthesis or retrolisthesis at the involved level(s). The Peekplus® devices are to be used with autogenous bone graft material and supplemental fixation.

Technological Characteristics
The Peekplus® Interbody Fusion Device is manufactured for Vallum Corporation by Binder Biomedical, Inc. and is identical to the Intervertebral Body Fusion Device cleared in K093015. The Peekplus® is comprised of a series of PEEK-OPTIMA® spacers shaped to accommodate autogenous bone graft and anatomical variation at different spinal levels. The Peekplus® also has a series of ridges on its superior and inferior surfaces to improve fixation and prevent migration. The Peekplus® is provided non-sterile.

Performance Data
Additional performance testing was not conducted in this submission, however, finite element analysis (FEA) was conducted to confirm a new worst-case was not created.

Basis of Substantial Equivalence
Both the Peekplus® Interbody Fusion Device and the Binder Biomedical Inc.'s Intervertebral Body Fusion Device cleared in K093015 are intended for use in intervertebral body fusion. The Peekplus® Interbody Fusion Device and the predicate device are indicated for use with autogenous bone graft in patients with degenerative disc disease ("DDD") at one or two spinal levels from L2-S1. The Peekplus® and its predicate are indicated for use in skeletally mature patients who have had at least six (6) months of non-operative treatment, and in patients who may have up to Grade 1 spondylolisthesis, retrolisthesis or previous non-fusion at the involved level(s). Thus, the indications for use for the Peekplus® are the same as those of the predicate and may be found substantially equivalent.

The Peekplus® Interbody Fusion Device and the predicate device share key technological characteristics. The PeekPlus® is manufactured for Vallum Corporation by Binder Biomedical, Inc. the holder of the 510(k) for the predicate device. All devices are made to the same specification, with the same drawings and have the same labeling. One minor additional manufacturing processing step is performed which does not impact the substantial equivalence of the devices as the process smooths the surface layer of the implants at depths measured in nanometers.

Therefore, the Peekplus® and the Binder devices both have the same intended use, the same indications for use, the same technological characteristics and principles of operation. In addition, the Peekplus® has the identical materials as the Binder device manufactured by the same manufacturer as the Binder devices. Thus, the Peekplus® is substantially equivalent to the predicate.